

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Peter Watts

Serial No: Continuation of 08/765,347

Express Mail Label  
No. EL 709 420 260 US

Filed: December 27, 2000

Date of Deposit: December 27, 2000

For: COLONIC DRUG DELIVERY COMPOSITION

BOX PATENT APPLICATION  
Assistant Commissioner of Patents  
Washington, D.C. 20231

**PRELIMINARY AMENDMENT**

Sir:

Prior to examination, please amend the application as follows.

**In the Specification**

On page 1, after the title, please insert the following paragraph:

--This application is a continuation of prior application U.S.S.N. 08/765,347 filed February 10, 1997, by Peter Watts, entitled "*Colonic Drug Delivery Composition*", which is a 371 of International Application No. PCT/GB95/01458 filed June 21, 1995, which claims priority to United Kingdom application 9412394.0 filed June 21, 1994.--

## **In the Claims**

### **Clean Copy of Amended Claims**

1. A drug delivery composition for delivering a drug to the colonic region comprising a starch capsule containing the drug and wherein the starch capsule is provided with a coating such that the drug is predominantly released from the capsule in the colon and/or terminal ileum, wherein the drug is not an immunosuppressive agent which is in solution.

8. A drug delivery composition according to claim 1 wherein the coating has a thickness in the range of 80  $\mu\text{m}$  to 300  $\mu\text{m}$ .

9. A drug delivery according to claim 1 wherein the drug is one which acts locally in the colon.

10. A drug delivery composition according to claim 1 wherein the drug is for systemic delivery and systemic action.

11. A drug delivery composition according to claim 1 wherein the drug is a vaccine for delivery to the lymphoid tissue of the colon.

13. A method of delivering a vaccine to the lymphoid tissue present in the colon of a human or mammal comprising orally administering a drug delivery composition comprising a starch capsule containing the vaccine and wherein the starch capsule is provided with a coating such that the vaccine is predominantly released from the capsule in the colon and/or terminal ileum, wherein the drug is not an immunosuppressive agent which is in solution.

### Marked Up Copy of Amended Claims

1. (Amended) A drug delivery composition for delivering a drug to the colonic region comprising a starch capsule containing the drug and wherein the starch capsule is provided with a coating such that the drug is predominantly released from the capsule in the colon and/or terminal ileum, wherein the drug is not an immunosuppressive agent which is in solution.

8. (Amended) A drug delivery composition according to [any one of the preceding claims] claim 1 wherein the coating has a thickness in the range of 80  $\mu\text{m}$  to 300  $\mu\text{m}$ .

9. (Amended) A drug delivery according to [any one of the preceding claims] claim 1 wherein the drug is one which acts locally in the colon.

10. (Amended) A drug delivery composition according to [any one of claims 1 to 8] claim 1 wherein the drug is for systemic delivery and systemic action.

11. (Amended) A drug delivery composition according to [any one of claims 1 to 8] claim 1 wherein the drug is a vaccine for delivery to the lymphoid tissue of the colon.

13. (Amended) A method of delivering a vaccine to the lymphoid tissue present in the colon of a human or mammal comprising orally administering a drug delivery composition comprising a starch capsule containing the vaccine and wherein the starch capsule is provided

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with a coating such that the vaccine is predominantly released from the capsule in the colon  
and/or terminal ileum, wherein the drug is not an immunosuppressive agent which is in solution.

Respectfully submitted,



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Date: December 27, 2000

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